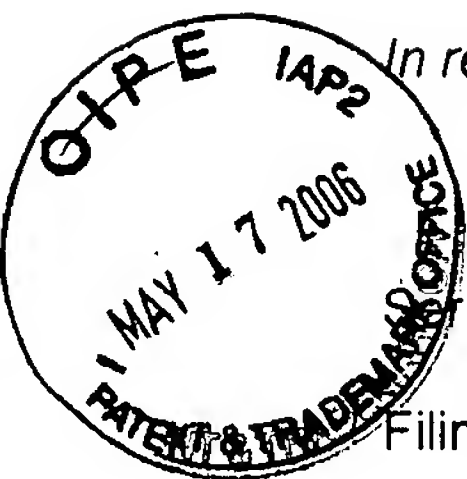


PATENT

Attorney Docket No. A-71386-7 RMS/TAW

Dorsey File No. 463077-00243

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re application of:

Lazar et al

Serial No.: 10/672,280

Filing Date: September 26, 2003

For: OPTIMIZED FC VARIANTS AND
METHODS FOR THEIR GENERATION

Examiner: Crowder, Chun

Art Unit: 1644

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450 on:

Dated: May 12, 2006

Signed: 
Victoria Linne Poulsen

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/08A. In accordance with 1287 Off. Gaz. Pat. Office 163, 10/19/2004, no copies of U.S. patents and U.S. published applications are enclosed.

Further, in satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and as required by M.P.E.P. § 2001.06(b), Applicant notes that the present application is related to the following pending patent applications:

1. U.S.S.N. 11/396,495, filed March 31, 2006;
2. U.S.S.N. 11/174,287, filed June 30, 2005;
3. U.S.S.N. 11/124,620, filed May 5, 2005;
4. U.S.S.N. 10/822,231, filed March 24, 2004;
5. U.S.S.N. 10/672,280 filed September 26, 2003;
6. U.S.S.N. 10/379,392 filed March 3, 2003 (now abandoned.)

Serial No.: 10/672,280
Filing Date: September 26, 2003

Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application. Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required.

While no fee is believed to be due, if this belief is in error, the Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2319 (File No.: 463077-00243); Docket No. A-71386-7).

Respectfully submitted,

DORSEY & WHITNEY LLP

Dated: Mar 12 / 2006

Customer Number 32940

Dorsey & Whitney LLP

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By:

Timothy A. Worrall
Timothy A. Worrall, Reg. No. 54,552 for
Robin M. Silva, Reg. No. 38,304

Filed Under 37 C.F.R. § 1.34

Attachments: Substitute PTO/SB/08A for Form 1449A/PTO
References
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Substitute for form 1449A/PTO
(Modified)**Complete if Known****INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

20

Application Number

10/672,280

Filing Date

September 26, 2003

First Named Inventor

Lazar et al.

Art Unit

1644

Examiner Name

Crowder, Chun

Attorney Docket Number

A-71386-7 (463077-00243)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US-2001/0036459 A1	11-01-2001	Ravetch	
	A2	US-2002/0004587 A1	01-10-2002	Miller, et al.	
	A3	US-2002/0048772 A1	04-25-2002	Dahiyat et al.	
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	A30	US-2004/0043429 A1	03-04-2004	Dahiyat et al.	

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			Application Number	10/672,280	
			Filing Date	September 26, 2003	
			First Named Inventor	Lazar et al.	
			Art Unit	1644	
			Examiner Name	Crowder, Chun	
Sheet	2		20	Attorney Docket Number	A-71386-7 (463077-00243)

U.S. PATENT DOCUMENTS					
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	A31	US-2004/0043430 A1	03-04-2004	Dahiyat et al.	
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			Art Unit	1644	
			Examiner Name	Crowder, Chun	
Sheet	3		20	Attorney Docket Number	A-71386-7 (463077-00243)

U.S. PATENT DOCUMENTS					
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	A62	US-4,816,397	03-28-1989	Boss, et al.	
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	A65	US-5,328,987	06-12-1994	Maliszewski	
	A66	US-5,541,087	07-30-1996	Lo, et al.	
	A67	US-5,576,184	11-19-1996	Better, et al.	
	A68	US-5,623,053	04-22-1997	Gastinel et al.	
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Sheet	4		20	Attorney Docket Number	A-71386-7 (463077-00243)

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	A91	US-6,528,624 B1	03-04-2003	Idusogie, et al.	
	A92	US-6,538,124 B1	03-25-2003	Idusogie, et al.	
	A93	US-6,632,927 B2	10-14-2003	Adair, et al.	
	A94	US-6,649,165 B1	11-18-2003	Schubert	
	A95	US-6,708,120 B1	03-16-2004	Mayo et al.	
	A96	US-6,719,971 B1	04-13-2004	Carter, et al.	
	A97	US-6,737,056 B1	05-18-2004	Presta	
	A98	US-6,792,356 B2	09-14-2004	Mayo et al.	
	A99	US-6,797,492 B2	09-28-2004	Daugherty, et al.	
	A100	US-6,801,861 B2	10-05-2004	Mayo et al.	
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	B1	WO 00/42072 A2, A3	07-20-2000	Genentech Inc		
	B2	WO 98/47089 A1	11-22-1998	California Institute of Technology		
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	B7	EP 1 255 826 B1	00-13-2002	Xencor, Inc.		
	B8	EP 0 268 636 B1	01-08-1997	McKenzie, I. F., et al.		
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Sheet	5		20	Attorney Docket Number	A-71386-7 (463077-00243)

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	B9	EP 0 383 799 B2	02-09-2005	Genentech, Inc.		
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	B11	EP 0 753 065 B1	05-14-2003	Celltech Therapeutics Limited		
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	B13	EP 0 888 125 B1	05-26-2004	Leung, S., et al.		
	B14	EP 0 904 107 B1	10-20-2004	Board of Regents, The University of Texas System		
	B15	EP 1 176 195 A1	01-30-2002	Kyowa Hakko Kogyo Co., Ltd.		
	B16	EP 1 229 125 A1	08-07-2002	Kyowa Hakko Kogyo Co., Ltd.		
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	B18	WO 00/09560 A2, A3	02-24-2000	Abgenix, Inc.		
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	B22	WO 01/38490 A2	05-31-2001	The Trustees of Columbia University in the City of New York		
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	B27	WO 02/30954 A1	04-18-2002	Kyowa Hakko Kogyo Co., Ltd.		
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	B29	WO 02/44215 A2	06-06-2002	Cockbain, J.		
	B30	WO 03/016470 A2	02-27-2003	University of Virginia Patent Foundation		
	B31	WO 03/035835 A2, A3	05-01-2003	Genentech, Inc.		
	B32	WO 03/054213 A2	07-03-2003	Genentech, Inc.		
	B33	WO 03/089624 A2	10-30-2003	UAB Research Foundation		
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			Application Number	10/672,280	
			Filing Date	September 26, 2003	
			First Named Inventor	Lazar et al.	
			Art Unit	1644	
			Examiner Name	Crowder, Chun	
Sheet	6		20	Attorney Docket Number	A-71386-7 (463077-00243)

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	B34	WO 04/004662 A2	01-15-2004	Genentech, Inc.		
	B35	WO 04/004798 A2, A3	01-15-2004	The Brigham and Women's Hospital, Inc., et al.		
	B36	WO 04/016750 A3	02-26-2004	Macrogenics, Inc		
	B37	WO 04/022717 A2, A3	03-18-2004	The Government of the United States of America as Represented by the Secretary of the Department of Health and Human Services		
	B38	WO 04/024871 A2	03-25-2004	Morphotek, Inc.		
	B39	WO 04/024889 A2	03-25-2004	Elusys Therapeutics, Inc.		
	B40	WO 04/035752 A2	04-29-2004	Protein Designs Labs, Inc.		
	B41	WO 04/056312 A2	07-08-2004	Genentech, Inc.		
	B42	WO 04/063351 A2, A3	07-29-2004	Macrogenics, Inc.		
	B43	WO 04/074455 A2, A3	09-02-2004	Applied Molecular Evolution		
	B44	WO 04/092219 A2	10-28-2004	Protein Design Labs, Inc.		
	B45	WO 04/103404 A1	12-02-2004	Applied Molecular Evolution		
	B46	WO 04/110472 A2	12-23-2004	Eli Lilly and Company		
	B47	WO 05/000899 A2	01-06-2005	Biogen Idec Ma Inc.		
	B48	WO 05/001025 A2	01-06-2005	Syntonix, Inc.		
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	B50	WO 05/011376 A2	02-10-2005	Biogen Idec Ma Inc.		
	B51	WO 05/012877 A2	02-10-2005	DNA Twopointo Inc.		
	B52	WO 05/116078 A1	12-08-2005	Medexgen, Inc.		
	B53	WO 05/013090 A2	02-10-2005	DNA Twopointo Inc.		
	B54	WO 05/018572 A2	03-03-2005	Biogen Idec Ma Inc.		
	B55	WO 05/023866 A2	03-17-2005	Baxter International Inc.		
	B56	WO 05/027966 A2	03-31-2005	Genentech, Inc.		
	B57	WO 05/037867 A1	04-28-2005	Protein Design Labs Inc.		

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				Filing Date	September 26, 2003
				First Named Inventor	Lazar et al.
				Art Unit	1644
				Examiner Name	Crowder, Chun
Sheet	7		20	Attorney Docket Number	A-71386-7 (463077-00243)

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	B58	WO 05/040217 A2	05-06-2005	Cambridge University Technical Services Limited		
	B59	WO 05/047327 A2	05-26-2005	Biogen Idec Ma Inc.		
	B60	WO 05/060642 A2	07-07-2005	Alexion Pharmaceuticals, Inc.		
	B61	WO 05/063815 A2	07-14-2005	Biogen Idec Ma Inc.		
	B62	WO 05/070963 A1	08-04-2005	Applied Molecular Evolution, Inc.		
	B63	WO 05/116078 A1	12-08-2005	Medexgen Inc.		
	B64	WO 05/123780 A2	12-29-2005	Protein Design Labs, Inc.		
	B65	WO 06/012500 A2	02-02-2006	Genentech, Inc.		
	B66	WO 88/07089 A1	09-22-1988	Medical Research Council		
	B67	WO 91/06305 A1	05-16-1991	Bristol-Meyers Squibb Company		
	B68	WO 91/19515 A1	12-26-1991	The Board of Trustees of the Leland Stanford Junior University		
	B69	WO 92/04053 A1	03-19-1992	Bristol-Myers Squibb Company		
	B70	WO 92/16562 A1	10-01-1992	Lynxvale Limited		
	B71	WO 92/22324 A1	12-23-1992	Xoma Corporation		
	B72	WO 94/29351 A2, A3	12-22-1994	Celltech Limited		
	B73	WO 95/05468 A1	02-23-1995	Lynxvale Limited		
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	B75	WO 97/28267 A1	08-07-1997	Repligen Corporation		
	B76	WO 97/34631 A1	09-25-1997	Board of Regents, The University of Texas System		
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	B78	WO 98/23289 A1	06-04-1998	The General Hospital Corporation		
	B79	WO 99/04813 A1	02-04-1999	Brigham & Women's Hospital, Inc., et al.		
	B80	WO 99/51642 A1	10-14-1999	Genentech, Inc.		
	B81	WO 99/54342 A1	10-28-1999	Umana, P., et al.,		

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	B82	WO 99/58572 A1	11-18-1999	Cambridge University Technical Services Limited		
	B83	WO 98/05787 A1	02-12-1998	Bristol-Meyers Squibb Company		

NON PATENT LITERATURE DOCUMENTS			
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	C1	ALGRE, et al., "A non-activating "humanized" anti-CD3 monoclonal antibody retains immunosuppressive properties in vivo," <i>Transplantation</i> , 57:1537-1543 (1994).	
	C2	ARMOUR, et al., "Recombinant human IgG molecules lacking Fc gamma receptor I binding and monocyte triggering activities," <i>Eur J Immunol</i> , 29:2613-2624 (1999).	
	C3	ASHKENAZI, et al., "Immunoadhesins as research tools and therapeutic agents," <i>Curr Opin Immunol</i> , 9:195-200 (1997).	
	C4	CHAMOW, et al., "Immunoadhesins: principles and applications," <i>Trends Biotechnol</i> , 14:52-60 (1996).	
	C5	DAVIES, et al. "Expression of GnTIII in a recombinant anti-CD20 CHO production cell line: Expression of antibodies with altered glycoforms leads to an increase in ADCC through higher affinity for FC gamma RIII," <i>Biotechnol Bioeng</i> , 74:288-294 (2001).	
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	C7	JEFFERIES, et al., <i>Immunol Lett</i> , 54:101-104 (1996).	
	C8	KRAPP, et al., "Structural analysis of human IgG-Fc glycoforms reveals a correlation between glycosylation and structural integrity," <i>J Mol Biol</i> , 325:979-989 (2003).	
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			Examiner Name	Crowder, Chun	
Sheet	9		20	Attorney Docket Number	A-71386-7 (463077-00243)

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	C15	AASE, A. et al. "The extended hinge region of IgG3 is not required for high phagocytic capacity mediated by Fc gamma receptors, but the heavy chains must be disulfide bonded," <i>Eur J Immunol.</i> , 23(7):1546-1551 (July 1993).	
	C16	ABADEH, S., et al., "Remodelling the oligosaccharide of human IgG antibodies: effects on biological activities," <i>Biochem Soc Trans.</i> , 25(4):S661 (November 1997).	
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	C21	ASHKENAZI, A., et al., "Mapping the CD4 binding site for human immunodeficiency virus by alanine-scanning mutagenesis," <i>PNAS, USA</i> , 87:7150-7154 (September 1990).	
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	C23	BORUCHOV, A. M., et al., "Activating and inhibitory IgG Fc receptors on human DCs mediate opposing functions" <i>J. Clin. Invest.</i> doi:10.1172/JCI24772 (September 16, 2005).	
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	C33	CARPENTER, P. A., et al., "Non-Fc Receptor-Binding Humanized Anti-CD3 Antibodies Induce Apoptosis of Activated Human T Cells," <i>Journal of Immunology</i> , 165:6205-6213 (2000).	
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			First Named Inventor	Lazar et al.	
			Art Unit	1644	
			Examiner Name	Crowder, Chun	
Sheet	11		20	Attorney Docket Number	A-71386-7 (463077-00243)

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	C52	DAVIS, R. S., et al., "Identification of a family of Fc receptor homologs with preferential B cell expression," <i>PNAS, USA</i> , 98(17):9772-9777 (August 2001).	
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Sheet	12		20	Attorney Docket Number	A-71386-7 (463077-00243)

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			Application Number	10/672,280
			Filing Date	September 26, 2003
			First Named Inventor	Lazar et al.
			Art Unit	1644
			Examiner Name	Crowder, Chun
Sheet	15	20	Attorney Docket Number	A-71386-7 (463077-00243)

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	C126	NIWA, R., et al., "Defucosylated Chimeric Anti-CC Chemokine Receptor 4 IgG1 with Enhanced Antibody-Dependent Cellular cytotoxicity Shows Potent Therapeutic Activity to T-Cell Leukemia and Lymphoma," <i>Cancer Research</i> , 64:2127-2133 (March 15, 2004).	
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	C143	RAVETCH, J. V., et al., "Immune Inhibitory Receptors," <i>Science</i> , 290:84-89 (October 6, 2000).	
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	C161	SONDERMAN, P., et al., "Human Fc γ Receptor IIb Expressed in <i>Escherichia coli</i> Reveals IgG Binding Capability" <i>Biol. Chem.</i> 380:717-721 (June 1999).	
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	C197	CHADD, H., et al., "Therapeutic antibody expression technology," <i>Curr. Opin. Biotech.</i> , 12:188-194 (2001).	
	C198	CLARK, M. "Antibody humanization: a case of the 'Emperor's new clothes?'" <i>Immunol. Today</i> , 21(8):397-402 (2000).	
	C199	CRAGG, M., et al., "Signaling antibodies in cancer therapy," <i>Curr. Opin. Immunol.</i> , 11:541-547 (1999).	
	C200	DALL'ACQUA, W., et al., "Antibody Engineering," <i>Curr. Opin Structural Biol.</i> , 8:443-450 (1998).	
	C201	GLENNIE, M., et al., "Clinical trials of antibody therapy," <i>Immun. Today</i> , 21(8):403-410 (2000).	
	C202	GLENNIE, M., et al., "Renaissance of cancer therapeutic antibodies," <i>Drug Discovery Today</i> , 8(11):503-510 (2003).	
	C203	HAYHURST, A., et al., "High-throughput antibody isolation," <i>Curr. Opin. Chem. Biol.</i> , 5:683-689 (2001).	
	C204	HOGARTH, P., "Fc receptors are major mediators of antibody based inflammation in autoimmunity," <i>Curr. Opin. Immun.</i> , 14:798-802 (2002).	
	C205	HOLLIGER, P., et al., "Antibodies come back from the brink," <i>Nature Biotechnology</i> , 16:1015-1016 (1998).	
	C206	HUDSON, P., "Recombinant antibody constructs in cancer therapy," <i>Curr. Opin. Immunology</i> , 11:548-557 (1999).	
	C207	HUDSON, P., "Recombinant antibody fragments," <i>Curr. Opin in Biotechnology</i> , 9:395-402 (1998).	
	C208	JOHNSON, G., et al., "Kabat Database and its applications: 30 years after the first variability plot," <i>Nucleic Acids Research</i> , 28(1):214-218 (2000).	
	C209	JOHNSON, G., et al., "Kabat Database and its applications: future directions," <i>Nucleic Acids Research</i> , 29(1):205-206 (2001).	
	C210	MAYNARD, J., et al., "Antibody Engineering," <i>Annu. Rev. Biomed. Eng.</i> , 2:339-376 (2000).	
	C211	MOREA, V., et al., "Antibody Modeling: Implications for Engineering and Design," <i>Methods</i> , 20:267-279 (2000).	
	C212	PENICHET, M., et al., "Antibody-cytokine fusion proteins for the therapy of cancer," <i>Journal of Immunological Methods</i> , 248:91-1010 (2001).	
	C213	REICHERT, J., "Monoclonal antibodies in the clinic," <i>Nature Biotechnology</i> , 19:819-822 (2001).	
	C214	THRUSH, G., et al., "Immunotoxins: An Update," <i>Ann. Rev. Immunol.</i> , 14:49-71 (1996).	
	C215	TORPHY, T., et al., "Pharmaceutical biotechnology Monoclonal antibodies: boundless potential, daunting challenges – Editorial Overview," <i>Curr. Opin. Biotechnol.</i> , 13:589-591 (2002).	
	C216	TRAIL, P., et al., " Monoclonal antibody drug conjugates in the treatment of cancer" <i>Curr. Opin. Immunol.</i> , 11:584-588 (1999).	

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				Application Number	10/672,280
				Filing Date	September 26, 2003
				First Named Inventor	Lazar et al.
				Art Unit	1644
				Examiner Name	Crowder, Chun
Sheet	20		20	Attorney Docket Number	A-71386-7 (463077-00243)

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	C217	TRIKHA, M., "Monoclonal antibodies as therapeutics in oncology," <i>Curr. Opin. Biotech.</i> , 13:609-614 (2002).	
	C218	VAN DIJK, M., et al., "Human antibodies as next generation therapeutics," <i>Curr Opin. Chem. Biol.</i> , 5:368-374 (2001).	
	C219	VAN SORGE, N., et al., "Fcγ R polymorphisms: Implications for function, disease susceptibility and immunotherapy," <i>Tissue Antigens</i> , 61:189-202 (2003).	
	C220	VASSEROT, A., et al., "Optimization of protein therapeutics by directed evolution," <i>Drug Discovery Today</i> , 8(3):118-126 (2003).	
	C221	WALDMANN, T., et al., "Emerging Therapies: Spectrum of Application of Monoclonal Antibody Therapy," <i>Hematology</i> , 394-408 (2000).	

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